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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,442	03/07/2002	Masafumi Tsujimoto	001560-332	9751

7590 06/03/2004  
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/091,442	Applicant(s) TSUJIMOTO ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 22-27 and 30-37 is/are pending in the application.  
     4a) Of the above claim(s) 1-15 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/091,028.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Applicants amendment filed March 5, 2004 has been received and entered. Claims 16-21, 28 and 29 have been canceled and new claims 34-37 have been added. Consequently, claims 1-15, 22-27, 30-37 are pending in the instant application, of which claims 1-15, and 22-27 have been withdrawn from further consideration as being drawn to a non-elected invention.

This application contains claims 1-15 and 22-27 drawn to an invention nonelected with traverse in the response filed June 30, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Objections***

1. The objection of claims 28-29 under 37 CFR 1.75(c) as being in improper form because claim cannot depend upon different sets of claims for different features is withdrawn in view of the cancellation of said claims.

### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 20-21, 28, 31 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro production of a megakaryocyte differentiation factor in a host cell, does not reasonably provide enablement for production of this factor in any cell is withdrawn in view of Applicants amendment.

3. The rejection of claims 30-33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Additionally, this rejection is applied to newly added claims 34-37.

Applicants are asserting that the common attributes may be delineated in part by the representative nucleotide sequence SEQ ID NO: 30 and in part by the amino acid sequence found in SEQ ID NO: 34. Applicants assert that they have identified the sequence of SEQ ID NO: 34 and an exemplary nucleotide sequence (e.g., SEQ ID NO: 30) in the genus encoding the amino acid sequence of SEQ ID NO: 34. The nucleotide trimer combinations that encode each individual amino acid are limited and well known. Applicants further assert that the courts have recently clarified that not all functional descriptions of genetic material fail to meet the written description requirement. *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 65 USPQ2d 1385, 1398 (Fed. Cir. 2003); *Enzo Biochem Inc. V. Gen Probe Inc.*, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the common attributes may be delineated in part by the representative nucleotide sequence SEQ ID NO: 30 and in part by the amino acid sequence found in SEQ ID NO: 34. However, Applicants are reminded that the written description requirement is not being questioned for SEQ ID NO: 30 or SEQ ID NO: 34.

Indeed, each of these sequences fully define a structure of a biological molecule which satisfies the requirements of the written description provision. However, the claims encompass other molecules of undefined structure based upon the limitation of "hybridizes with a polynucleotide encoding the amino acid sequence of SEQ ID NO: 34." It is these cross hybridizing molecules which have not been described in any shape or form beyond the mere mention that they are part of the invention. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. *Fiers. v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Second, Applicants assert that they have identified the sequence of SEQ ID NO: 34 and an exemplary nucleotide sequence (e.g., SEQ ID NO: 30) in the genus encoding the amino acid sequence of SEQ ID NO: 34, and that nucleotide trimer combinations that encode each individual amino acid are limited and well known. However, again the description of SEQ ID NO: 30, and even degenerate variants of SEQ ID NO: 30 are not being questioned. However, hybridizing molecules have not been described in any manner beyond the mere mention that they are part of the invention. Accordingly, this statement alone does not provide a basis for satisfying the provision of the written description requirement.

Finally, Applicants assert that the courts have recently clarified that not all functional descriptions of genetic material fail to meet the written description requirement. *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 65 USPQ2d 1385, 1398

(Fed. Cir. 2003); *Enzo Biochem Inc. V. Gen Probe Inc.*, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002). However, as set forth in *Amgen Inc. v. Hoechst Marion Roussel, Inc.* 65 USPQ2d 1385, 1398 (Fed. Cir. 2003); terms that “readily convey distinguishing information concerning their identity, such that one of ordinary skill in the art could visualize or recognize identity of members of the genus” were deemed to satisfy the written description requirement. However, the instant application is not analogous since one of skill in the art would not have sufficient guidance to identify members of the genus. For instance, what level of homology is necessary, or what specific region of the sequence is necessarily present for biological activity to occur? Without such guidance, one of skill in the art would be unable to recognize members of the genus.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 30-31 under 35 U.S.C. 102(b) as being anticipated by Hermona et al is maintained.

Applicants are asserting that one of ordinary skill in the art would consider that it would be difficult for the DNA recited in the claims to hybridize with the DNA of the

Hermona et al publication. Applicants assert that the similarity between the DNA sequence of Hermona et al and the DNA sequences presently claimed is about 22.5%.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that one of ordinary skill in the art would consider that it would be **difficult** for the DNA recited in the claims to hybridize with the DNA of the Hermona et al publication. (Emphasis added). However, Applicants are again directed to the claims. There are no requirements as to what hybridization conditions are employed. Furthermore, there is simply no requirement of a wash step. Consequently, any DNA molecule which is capable of forming even a very weak hybridization (i.e., difficult to achieve) is deemed anticipatory of the claimed invention.

Finally, Applicants assert that the similarity between the DNA sequence of Hermona et al and the DNA sequences presently claimed is about 22.5%. However, as set forth above, even a weak temporary hybridization is all that is required. Furthermore, the claims do not recite a minimum level of sequence identity which must be present, accordingly 22.5% is sufficient.

The claims are directed to an isolated DNA coding for a megakaryocyte differentiation factor which stimulates differentiation of megakaryocytes, wherein said DNA hybridizes with a polynucleotide encoding the amino acid sequence of SEQ ID NO: 34.

Hermona (EP 354989) disclose of isolated DNA encoding a megakaryocytopoeitin, as well as vectors, host cells, and methods of expressing the protein recombinantly. (See abstract and claims).

In view that the DNA molecule disclosed by Hermona encodes a megakaryocyte differentiation protein which can hybridize to SEQ ID NO: 34 of the instant invention under certain conditions, the disclosure of Hermona is deemed to anticipate the claimed invention.

### ***Double Patenting***

5. The rejection of claim 16 and 18 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 3 of prior U.S. Patent No. 5,874,253 is withdrawn in view of the cancellation of said claims.

6. The rejection of claims 30-33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,874,253 is maintained. Additionally this rejection is applied to newly added claims 34-37.

Applicants have requested that this rejection, as it applies to the remaining claims be held in abeyance until the claims of the present application are otherwise allowable. However, until a terminal disclaimer is made of record, this rejection is maintained for reasons of record.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
May 25, 2004